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10/585,606	05/17/2007	Thorsten Bechert	21270-002US1	7193
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FISH & RICHARDSON P.C.			LEWIS, KIM M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/585,606	Applicant(s) BECHERT ET AL.	
	Examiner Kim M. Lewis	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29 and 31-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 31-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 9/29/08 has been received and made of record. As requested, claims 26, 31 and 39 have been amended, and claim 30 has been cancelled.
2. Claims 26-29 and 31-59 are pending in the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 26-29, 31 and 34-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0176827 ("Chandra et al.") in view of U.S. Patent No. 6,087,549 ("Flick") and U.S. Patent Application Publication No. 2002/0045049 ("Madsen").

Re. claim 26, Chandra et al. disclose a wound dressing comprising a vapor permeable, liquid impermeable backing (12) having an antimicrobial metal containing absorbent (14) and an adhesive (16) thereon for adhering the dressing to the skin. Chandra et al. fails to teach that the metal is in the form of clusters, and a hydrophilic polymer on the surface of the absorbent.

As to the cluster, the prior art is replete with textile materials impregnated/coated with silver clusters, note for example Flick. Flick discloses a multilayer laminate wound dressing that comprises a plurality of layers of silver or silver-coated fibers in a woven fabric (abstract). Flick also discloses at col. 9, lines 1-3, that the silver is "...a mixture of ionic and metallic forms of silver. The metallic form are clusters of silver ranging from 20 to 10,000 atom clusters." Thus, it would have been obvious to one having ordinary skill in the art to substitute the type of silver used in Chandra et al. for the mixture of silver, which includes clusters, of Flick as an obvious design choice since Applicants

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claim a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results. Applicants should note that it has been held that where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007) (citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007) (citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396).

Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

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As to the hydrophilic polymer, Madsen discloses a hydrophilic coating which may be used on medical devices including wound dressings (para. 0027) for the purpose of reducing friction/abrasion against the living tissue.

In view of Madsen, it would have been obvious to one having ordinary skill in the art to provide a hydrophilic coating on the wound dressing, particularly the absorbent material, of Chandra et al. In order to reduce friction/abrasion against the living tissue on which it is applied.

As to the adhesive, Chandra et al. do not disclose that the adhesive (14) surrounds the matrix, thereby providing an island-type dressing. However, such configurations are well known and used in the art to prevent unwanted bacteria from entering through side edges of the wound dressing.

The prior art is replete with island-type dressings. Thus, it would have been obvious to one having ordinary skill in the art to provide the modified dressing of Chandra et al. with an adhesive surrounding the matrix in order to seal the dressing from outside contaminants such as bacterial.

As to the backing layer, Chandra et al. do not teach the layer is a film. However, liquid impermeable, vapor permeable films are well known in the art. Thus, it would have been obvious to one having ordinary skill in the art to construct the backing from a liquid impermeable, vapor permeable film since they are well known and cheap.

Re. claims 27-29, it is inherent that the anti-microbial substance is bound exclusively to a surface of the silver containing fibers (para. 0047 of Chandra et al.)

Re. claim 30, Chandra et al. disclose in para. 0047, that the textile matrix (absorbent) is constructed from silver-plated nylon fibers. It is inherent that the silver particles are provided in clusters since the fibers are coated.

Re. claim 31, in a product claim, the method by which the product is formed is not germane to the issue of patentability, thus the limitation of how the metal is applied to the matrix is disregarded.

Re. claim 29, the mean particle size of the silver is not known. It has been held that the optimization of proportions in a prior art device is a design consideration within the skill of the art. *In re Reese*, 290 F. 2d 839, 129 USPQ 184 (CCPA 1961). Thus, the examiner contends that the optimization of the particle size of the silver would have been an obvious design choice within the level of ordinary skill in the art

Re. claim 34, the silver is activated by soaking of the matrix in wound exudate.

As regards claims 35-39, Madsen discloses that the hydrophilic coating may contain silver in order to reduce bacteria such as *Staphylococcus*, a gram negative bacterium. Since the coating may contain an antibacterial such silver, it necessarily reduces the adhesion of bacteria to the matrix. Madsen, however, fails to disclose that the coating is provided by plasma polymerization and that the coating is oxidized after plasma polymerization. Applicant is reminded that in a product claim the method of forming the product is not germane to the issue of patentability and is thus disregarded.

Re. claims 40-41, Madsen fails to teach the recited hydrophilic coating. Absent a critical teaching and/or a showing of unexpected results derived from the use of hydrophilic polymers, such as hexamethyldisiloxane, the examiner contends that the

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use of any known hydrophilic polymer coating that allows the release of silver ions would have been obvious to one having ordinary skill in the art. Thus, the use of hexamethylsiloxane does not patentably distinguish applicant's invention.

As regards claim 42, the mean thickness of the hydrophilic coating is not known from Madsen. However, applicant should note that it has been held that when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely that the product is not of innovation, but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it obvious under 35 USC 103. *KSR Int'l Co. v. Teleflex, Inc.* 127 S. CT. 1727, 1742, 82 USPQ2d 1385, 1396 (2207). In light of the need to reduce friction/abrasion, it would have been obvious to one having ordinary skill in the art to try a broad range of hydrophilic coating thickness to provide the modified device of Chandra et al. with a coating thickness necessary to reduce friction/abrasion of the metal coated fibers and absorbent fibers.

As regards claim 43, the amount of silver present is not acting cytotoxically on the wound (note the blend amount in para. 0009, coating amount in para. 0015 and wound healing effects in paras. 0041-0045).

Re. claim 44, note para. 0040, which discloses additional wound healing substances.

Re. claims 45-58, the modified device of Chandra et al. fail to teach the recited claim limitations. However, none of the recited limitations, for example, a transparent

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film backing, pH indicator, sensor, etc., are novel and therefore do not add anything novel to the claim from which it depends. In fact, the addition of the recited features of claims 45-58, to the modified device of Chandra et al. would have been obvious to one having ordinary skill in the art in order to achieve a desired effect.

Re. claim 59, note the rejection of claim 26 above. In further regard to claim 59, Madsen fails to teach the hydrophilic polymer coating is provided by plasma polymerization. However, such a coating technique is known and used in the art. Thus, it would have been obvious to one having ordinary skill in the art to use any well known coating techniques absent a critical teaching.

7. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chandra et al. in view of Flick and Madsen as applied to claim 26, and in further view of U.S. Patent No. 7,005,556 ("Becker et al.").

As regards claim 33, the modified device of Chandra et al. fails to teach the thickness of the silver coating. However, Becker et al. disclose a wound dressing comprising silver coated fibers. Becker et al. disclose that the silver coating thickness may vary broadly (col. 4, lines 45-59). Thus, it would have been obvious to one having ordinary skill in the art to vary the thickness of the coating on the silver fibers of the modified dressing of Chandra et al. depending upon the desired specific resistance.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

kml
December 27, 2008